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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,099	10/03/2001	Cynthia C. Bamdad	M01015/70066 TJO	2127
JHK Law P.O. Box 1078 La Canada, CA 91012-1078			EXAMINER DO, PENSEE T	
			ART UNIT	PAPER NUMBER
			1641	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/971,099

Applicant(s)

BAMDAD, CYNTHIA C.

Examiner

Pensee T. Do

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18, 20-29, 35, 36 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 22-29, 40 and 41 is/are allowed.
- 6) ☒ Claim(s) 13-18, 20-21, 35-36, 42-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry & Claim status

The amendment filed on December 08, 2006 has been acknowledged and entered.

Claims 13-18, 20-29, 35, 36, 40-43 are pending.

Maintained Rejection(s)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-21, 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite for reciting "the first article being immobilized relative to a signaling entity that is immobilized relative to a binding partner". The binding partner is already linked to a first agent and a nanoparticle being linked to a binding partner. Where else on the binding partner would a signaling entity bind? Where is the signaling entity with respect to the nanoparticle and the first agent?

Also, claim 13 is indefinite because it is unclear whether the signaling entity is the same as or different from the nanoparticle.

Claim 13 is also confusing about the purpose of magnetically drawing the second article and subsequently releasing it.

Claim 13 is also unclear of how the first and the second locations are differed in order to distinguish which location has the first article from which location has the second article.

Claim 13 fails to recite a device or a surface that contains the first and the second locations. Such device is important to the method of the claim because it is the device, presumably, which determines which location has the first and which location has the second article in order to carry out the releasing step or the separation step.

Claim 17 is indefinite for reciting "predetermined surface areas" in line 3, which have not been recited or introduced in the independent claim 13, or claims 15 and 16. It is unclear that whether the predetermined surface areas are the same as the first and second locations.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18, 20, 21 and 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. A step of determining whether the nanoparticles are present in first and second locations after magnetically drawing the first and second articles to the first and second locations is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification, page 13, lines 7-24, describes that "Pools of drug-presenting magnetic beads are then mixed with colloids that present both the target molecules and

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an electronic label. The solution is retained over an array of microelectrodes. A magnetic field can be separately applied to each electrode in the array to attract magnetic beads. ***The array is then electronically analyzed (ACV preferred). Pads that register a positive, indicate that, at that address/location, a drug candidate on a magnetic bead has captured a target molecule on a signaling colloid. The magnetic field at spatial addresses that registered a positive remain "turned on", while the other magnetic fields are released, and an exit valve is opened to wash away magnetic bead...***". (emphasis added). However, the claims fail to recite such step of electronically analyzing the nanoparticle/colloids on the magnetic particles after magnetically attracting the magnetic beads to the surface of the locations. Without such step recited in the claim, it would be impossible to distinguish the first articles from the second articles because these article both contain magnetic particles which would attract to the surface or locations that were applied with a magnetic field. The differential component between the first and second articles is the nanoparticles on the first article. Thus, one would take advantage of such nanoparticles/signaling entity in order to distinguish the first article from the second article.

Response to Arguments

Applicant's arguments filed December 08, 2006 have been fully considered but they are not persuasive.

Regarding 112, 2nd paragraph rejection pertaining to the phrase "the first article being immobilized relative to a signaling entity that is immobilized relative to the

binding partner", Applicant fail to see how this phrase is indefinite and would like further clarification as to the reason for the rejection. The sequence of binding is clear.

The first article as defined in claim 13, to comprise:

- a magnetic bead
- a first chemical/biological agent being fastened to the first article
- a binding partner of the first agent linked to the first agent
- a nanoparticle being linked to the binding partner.

Since the first article is defined to comprise all the components listed above which include the binding partner (emphasized above) and such binding partner is bound to a first agent and a nanoparticle, where else on such binding partner would a signaling entity bind?

Applicants have not responded to the other 112, 2nd paragraph rejections.

Therefore, all other 112, 2nd paragraph rejections are still maintained.

Regarding the 112, 1st paragraph rejection that a step of determining whether the nanoparticles are present in first and second locations after magnetically drawing first and second articles to the first and second locations is critical, Applicants argue that they do not understand this rejection as the claimed invention can be carried out using a variety of signaling entities attached to the nanoparticle. For example oligonucleotides or metallocenes or visual inspection may be used to practice the claimed invention. Thus, it is not necessary to electronically analyze the nanoparticles/colloids on the magnetic particles.

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The missing step is actually a step of "determining whether the nanoparticles are present in the first or second locations after magnetically drawing the first and second articles to their locations". In other words, a step of detecting the signaling entity on the magnetic particles to distinguish which magnetic particle or which location has a nanoparticle bound thereto in order to release the unbound magnetic particle (second article). The description in the specification at page 13 is just an example that a step of determining the signaling entity.

Remarks

Claims 13-18, 20-29, 35, 36 and 40-43 are free of prior arts as now recited.

Claims 22-29, 40 and 41 are allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
March 2, 2007


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600